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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hasler, et al.

Art Unit : 1645

Serial No. : 09/355,220

Examiner : Jennifer E. Graser

Filed : October 6, 1999

Title : NOVEL METHOD FOR THE ISOLATION OF POLYSACCHARIDES

United States Patent and Trademark Office
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RESPONSE TO OFFICE ACTION

In response to the Office Action mailed December 4, 2002, in connection with the above-identified application, the time for responding having been extended to April 4, 2003, by the accompanying fee and petition under 37 C.F.R. §1.136, Applicants respectfully request consideration of the following remarks and allowance of Claims 23 to 36.

REMARKS

These remarks are in response to the Final Office Action mailed December 4, 2002. Claims 23 to 36 are pending and under examination.

Rejection Under 35 U.S.C. § 103(a)

Claims 23 to 36 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Gotschlich *et al.* (*J. Exp. Med.* 129:1349 (1969)) or Schneerson *et al.* (*J. Exp. Med.* 152:361 (1980)) in view of Hou *et al.* (*J. Parenteral Science and Technology* 44:204 (1990)) and Lewis (U.S. Patent No. 5,589,591). Applicants traverse this rejection. Applicants submit that the

Examiner has not established a *prima facie* case of obviousness by combining these references and therefore, the rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See*, MPEP §§ 2142, 2143. In the present case, none of the criteria for a *prima facie* case of obviousness has been satisfied and therefore, the claim rejection under 35 U.S.C. §103(a) should be withdrawn.

The combination of prior art references do not teach or suggest all the claim limitations

Applicants suggest that the criterion that the combination of prior art references must teach or suggest all the claim limitations should be regarded as the threshold criterion for establishing a case of *prima facie* obviousness. If the combination of cited reference does not teach the claimed invention, then questions of motivation or suggestion to combine, or questions of reasonable expectation of success, are rendered moot. Therefore, Applicants would like to address this criterion first.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In the present case, no cited reference or combination of references teaches all the claim limitations. No cited reference or combination of references teaches the steps of mixing a bacterial polysaccharide fraction with a detergent solution, addition of alcohol to a final concentration which is below the concentration at which the polysaccharide precipitates, mixing the solution, filtering the solution by way of a deep bed filter, and separation of the polysaccharide from detergent and alcohol.

No suggestion or motivation to combine references to make the claimed invention

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988); *In re Jones* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See generally, MPEP §2143, especially §2143.01. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In the present case, there is no teaching or suggestion to combine or modify the cited references in such a way as to produce the claimed invention. In addition, there is no motivation to combine or modify the cited references to produce the claimed invention because each of the methods described in the cited references is complete in itself, *i.e.*, each method is capable of being used to isolate polysaccharides or remove endotoxins without modifying, substituting or adding steps. As the methods described in the cited references are complete in themselves, there is no motivation for the skilled artisan to modify the methods, add steps of one method to steps of another method or to substitute steps of one method with steps of another method.

In this regard, the Federal Circuit has held that even in situations where the combination of references taught every element of the claimed invention, without a motivation to combine the references, a rejection under 35 U.S.C. §103(a) is improper. *In re Rouffet* 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Federal Circuit has held that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Further, the argument that a combination is "obvious to try" is not acceptable for establishing obviousness. *In re Tomlinson* 150 USPQ 623 (CCPA 1966). Finally, absent a suggestion, teaching, or motivation to combine references, such a combination is unacceptable "hindsight" that does not establish a *prima facie* case of obviousness. *In re Dembiczak* 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

Because there is no teaching, suggestion, or motivation to combine or modify the cited references to produce the invention of Claims 23 to 36, this criterion for establishing a *prima facie* case of obviousness has not been satisfied, and the rejection should be withdrawn.

No reasonable expectation of success

Prima facie obviousness requires a reasonable expectation of success. In the present case, the cited reference provide no reasonable expectation of success. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants maintain that the cited references, alone or in combination, do not even teach the claim limitations. However, even if for the sake of argument it was supposed that the cited references taught the claim limitations, the cited references nonetheless do not provide a reasonable expectation of success because they do not teach or suggest there is any advantage modifying or combine the steps of these references to produce the claimed invention. For example, Hou *et al.* describe endotoxin removal employing ultrafiltration or a depth type filter (see, page 204, left column, second paragraph), but do not teach or suggest that a depth type filter is any more effective than ultrafiltration for removing endotoxin. Moreover, as acknowledged by the Examiner, Lewis also indicates that ultrafiltration may be used to remove endotoxin. In fact, Lewis appears to indicate that ultrafiltration is a preferred technique, *e.g.* as stated in the Abstract: "[s]uitable size separation techniques include gel filtration, or more preferably, ultrafiltration." The fact that Hou *et al.* and Lewis describe ultrafiltration and gel permeation chromatography demonstrate lack of reasonable expectation of success by teaching away from producing the claimed methods.

Regarding concentrations recited in Claims 30-32

According to the Office Action mailed December 4, 2002, the concentrations recited in dependent claims 30-32 are allegedly result effective variables and it would have been obvious

for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures. (Office Action, Section 2, page 4) Applicants traverse this rejection.

A particular parameter must first be recognized as a result-effective variable before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As discussed above, the cited prior art does not even disclose the claimed invention and therefore, the concentrations recited in Claims 30-32 were not recognized in the art as result-effective variables. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would not have been obvious for one of ordinary skill to discover the concentrations recited in Claims 30-32, because discovery of the concentrations recited in Claims 30-32 is not discovery of optimum workable ranges of methods disclosed by the prior art.

In sum, no *prima facie* case of obviousness has been established. The cited references fail to teach or suggest all the claim limitations of Claims 23-36. In addition, the cited references fail to teach or suggest combining or modifying the references to produce the claimed invention, or provide guidance as to how to combine or modify references to produce the claimed invention. Finally, the cited references fail to provide reasonable expectation of success from combining or modifying the methods in the cited references. Thus, it cannot objectively be stated that the skilled artisan could modify or combine the references in such a way as to produce the claimed methods, let alone that the skilled artisan would be motivated to combine these references or that there would be a reasonable expectation of success. Because none of the criteria for establishing a *prima facie* case of obviousness has been satisfied, the rejection under 35 U.S.C. §103(a) is improper and must be withdrawn.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that the pending claims clearly and patentably define the invention. Applicants respectfully request that the Examiner reconsider the various grounds set forth in the Office Action in light of the preceding Remarks and find Claims 23-36 in condition for allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4093.

Please charge any additional fees, or make any credits, to Deposit Account No. 03-3975.

Respectfully submitted,

Date:

April 3, 2003


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